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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

PHILLIP RACIES, On Behalf of Himself and All Others Similarly Situated, Plaintiffs, vs. QUINCY BIOSCIENCE, LLC, a Wisconsin limited liability company, Defendant.	Case No. 3:15-cv-00292-HSG **PLAINTIFF'S RESPONSE TO MOTION FOR SUMMARY JUDGMENT OF DEFENDANT QUINCY BIOSCIENCE, LLC** Date: February 4, 2016 Time: 2:00 p.m. Courtroom: 15-18th Floor 450 Golden Gate Avenue San Francisco CA 94102 Judge: Hon. Haywood S. Gilliam Jr. Complaint Filed: January 21, 2015 Trial Date: None Set

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I. INTRODUCTION

At the very beginning of its Memorandum of Points and Authorities in support of its motion for summary judgment (D.E. 55), Defendant makes a critical misstatement that causes the remainder of its arguments to spin out of control and veer off course. Defendant accurately quotes from this Court's Order on Defendant's motion to dismiss where it states that in order to prevail in this case, Plaintiff must prove his body chemistry allegations and that "the apoaequorin in the product is destroyed by the human digestive system or is of such a trivial amount that it cannot biologically affect memory or support brain function." (D.E. 55, p. 1 (quoting D.E. 34, p. 6).) But that is where the accuracy stops. Defendant then states that based upon the above quote "the only issue before this Court in the present motion is whether the apoaequorin ('AQ') in Prevagen® is completely destroyed via digestion and/or incapable of passing through the blood brain barrier ('BBB')." (D.E. 55, p. 1.)

This, of course, is a complete misinterpretation of the Court's Order. Plaintiff does not have to prove that AQ is *completely* destroyed or totally incapable of passing through the BBB. That is certainly one means by which Plaintiff can prove his claims, but not the only means. Nonetheless, even if it were, as shown below, Plaintiff has, at a minimum, met his burden to defeat Defendant's "no evidence/*Celotex*" style motion on these issues for at least three reasons: (1) in a document submitted to the FDA, Defendant has admitted that AQ is not only completely digested but that it is digested solely into amino acids, thereby making the product of its digestion indistinguishable from any other dietary proteins; (2) Plaintiff's expert has opined that, based upon well-settled scientific principles and a vast weight of scientific literature, it is well-established that dietary proteins like AQ are digested into amino acids or amino acids and possibly some small peptides, making the products of its digestion indistinguishable from any dietary protein; and (3) even if some intact AQ molecules could somehow survive digestion, based upon another set of well-settled scientific principles and a vast weight of scientific literature, it is well-established that dietary proteins and molecules like AQ cannot pass through the BBB.

Defendant attempts to mischaracterize Plaintiff's expert, Dr. Bazinet's, testimony, twisting it well beyond its meaning, asserting such things as that he has not foreclosed the possibility that some intact AQ molecules could escape digestion and that he has not foreclosed the possibility that some of these molecules might somehow pass through the BBB. But, as shown below, as to the probability of each of these possibilities, Dr. Bazinet clearly stated that they were next to zero.

But, putting aside their misconstructions of his testimony, the fact is that, at best, the arguments that Defendant builds upon these false premises go to the weight of Dr. Bazinet's testimony and most certainly do not and cannot result in a complete nullification of his opinions. All Defendant does is skip around the far edges of his opinions, and after having asked open-ended questions to which Dr. Bazinet truthfully answered, argues that he admits that it is a "possibility" of this or that. But what Defendant fails to tell the Court is that Dr. Bazinet also stated that these "possibilities" were remote and next to zero and that after all of the questions and answers were given to Defendant's counsel's questions, Dr. Bazinet explained why the questions posed and the answers he gave during his cross examination did not affect his opinions in any manner. (Ex. A, Bazinet Dep. 305:16-306:6, 307:8-310:21, 311:22-312:19, 315:24-317:10, 318:11-324:1, 324:25-327:1).[1]

But this is not all that Plaintiff's expert has opined and it is this part of his opinions that Defendant ignores as a result of its misinterpretation of the Court's Order. Contrary to what Defendant contends this Court ordered, Plaintiff does not have to show that AQ is totally digested or that no AQ can ever cross the BBB. While he can prove and has proven[2] this to be the case, the Court also held that Plaintiff could prevail on his body chemistry allegations if the AQ that might

[1] Exhibit A is attached to the supporting Declaration of Patricia N. Syverson.

[2] It should be understood that Plaintiff does not need to prove his case in the context of Defendant's motion but his evidence must merely create material questions of fact. *See T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987) (quoting *First Nat'l Bank v. Cities Serv. Co.*, 391 U.S. 253, 288-89 (1968)) ("[T]he issue of material fact required by Rule 56(c) to be present to entitle a party to proceed to trial is not required to be resolved conclusively in favor of the party asserting its existence; rather, all that is required is that sufficient evidence supporting the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial.")

survive digestion and then possibly pass through the BBB "is of such a trivial amount that it cannot biologically affect memory or support brain function."

In his report, Dr. Bazinet, relying upon the very studies that Defendant purports to rely upon in documents that it produced, gives Defendant all benefit of the doubt and applies the results of these studies, involving very rare exceptions to the general rules of digestion and BBB permeability, to AQ and concludes that under the best of circumstances, whatever AQ might enter the brain would be so trivial it would be next to zero and have zero impact on the brain. (D.E. 56-1, Bazinet Report, ¶¶ 28-29.)

In its Memorandum, Defendant completely ignores this separate facet of Dr. Bazinet's opinions – opinions that clearly meet this Court's triviality test. For these, and other reasons set forth below, Defendant's motion should be denied because it is clear that, at a minimum, Plaintiff has presented more than sufficient evidence to support each of the body chemistry prongs that this Court set forth in its order on Defendant's motion to dismiss. In short, there is not an absence of proof on any issues.

II. ARGUMENT

A motion for summary judgment should only be granted when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (quotation omitted). A party seeking summary judgment bears the initial burden of informing the court of the basis for its motion and of identifying those portions of the pleadings and discovery responses that demonstrate the absence of a genuine issue of material fact. *Id.* Defendant claims that it is entitled to summary judgment because Plaintiff has failed to present affirmative evidence that the representations it makes about Prevagen are false. (D.E. 55, pp. 10-11.) As this response and Plaintiff's Motion for Partial Summary Judgment (D.E. 58 ("Plaintiff's Motion")) demonstrate, Plaintiff has presented more than enough evidence in support of the elements of his claims, and Defendant's Motion for

Summary Judgment should be denied.[3] In fact, as set forth in Plaintiff's Motion and as will be further explicated in his reply brief, now that the depositions of Defendant's experts have been taken, it is clear that Prevagen cannot have any effect on improving memory or brain function, and summary judgment should be entered in favor of Plaintiff.

As noted above, Defendant incorrectly asserts that it is entitled to summary judgment "[b]ecause there is no genuine issue of material fact that AQ, or a portion of it, is not completely destroyed via digestion and that it is possible for a portion of AQ to cross the BBB and affect brain function." (D.E. 55, p. 1.)

But even accepting this gauntlet, Defendant, in documents submitted to the FDA, has admitted that AQ is completely digested into amino acids. This admission, on its own, is enough to defeat Defendant's *Celotex*-based "lack of evidence" motion. But, as will be seen, Plaintiff's expert opinions, at a minimum, establish the same – that AQ is completely digested into amino acids or amino acids and possibly some small peptides, such that there are no AQ molecules left after digestion.

But even if Defendant's contentions were true and Dr. Bazinet could not preclude the mathematical possibility of some AQ surviving digestion, and then there being a mathematical possibility of some of these AQ molecules passing the BBB and entering the brain (all of which he has shown is not the case), Defendant's formulation of the issue ignores that Dr. Bazinet has also opined that under any "possible" circumstances and, giving Defendant all benefits of the doubt, the calculation of how much orally ingested AQ might actually get into the brain after ingestion would be trivial and not affect memory or brain function.

Avoiding these opinions altogether, which as noted above is fatal to its motion from the start, Defendant points to six "facts" that it argues contradict Dr. Bazinet's complete digestion and BBB impermeability opinions - opinions relating to the first prong by which Plaintiff could prove falsity as set forth by the Court. (D.E. 55, pp. 5-9.) Because responding to these "facts" is intricately tied to Plaintiff's response to Defendant's motion, limited as it is, each of Defendant's

[3] Plaintiff adopts Plaintiff's Motion and the reply in support that will be filed in accordance with the briefing schedule as further response to Defendant's motion.

claims is addressed here, in the argument section (rather than in a separate fact section), explaining how each of Defendant's "facts" fails to show what Defendant claims. Thus, even with respect to these limited issues, complete digestion and complete BBB impermeability, the record before the Court on Defendant's motion requires the denial of Defendant's motion.

A. Defendant cannot obtain summary judgment by, once again, mischaracterizing Plaintiff's claims as lack of substantiation claims.

Relying on *King Bio* and cases applying it (*id.*), Defendant argues that, like the plaintiff there, Plaintiff here has not presented evidence specific to AQ, but rather "a theory regarding dietary proteins in general, and not the product at issue." (D.E. 55, pp. 14-15.) This is just not so – Plaintiff has offered far more than mere theories; rather he has, among other things cited to studies specifically involving AQ that both a panel of experts hired by Defendant (prior to this litigation) and Defendant have relied upon to state to the FDA that AQ is digested solely into amino acids. Furthermore, Plaintiff's expert is not relying upon mere theories; as more fully set forth below he relies upon well-settled and universally accepted doctrines about the digestion of dietary proteins and the impermeability of the BBB – doctrines that are supported by a vast amount of scientific research and literature spanning since the 1800s. (Ex. A, Bazinet Dep. 324:25-327:1.)

Moreover, *King Bio* does not even stand for the proposition that in order to prove falsity a plaintiff must cite to and rely upon testing specific to the substance in question. The plaintiffs in *King Bio* did not posit any "theories" scientific or otherwise and instead argued that they could show that the defendant lacked substantiation for its claims and it was defendant's burden to substantiate its claims. *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm, Inc.*, 107 Cal. App. 4th 1336, 1341-42 (2003). While the court noted that the falsity of claims could be established by scientific testing, it also made clear that this was not the only means, as falsity can also be established by "scientific literature." *King Bio*, 107 Cal. App 4th at 1347-48.[4]

As Dr. Bazinet stated at his deposition, the evidence supporting his opinions on digestion and the BBB is so vast that it at least would involve 100,000 citations if not more. (Ex. A, Bazinet Dep. 324:25-327:1.) Thus, putting to the side for one moment Defendant's admission that AQ is

[4] As Defendant acknowledges (D.E. 55, p. 12).

digested solely into amino acids, at a minimum, Plaintiff and his expert have met the requirements of *King Bio* since they are relying upon the vast and well-accepted "scientific literature" regarding dietary proteins. A literature that establishes that AQ, like all other dietary proteins, is completely digested into common amino acids and possibly some small peptides and, furthermore, that AQ cannot pass through the blood brain barrier and enter the brain.[5]

B. There is, at a minimum, material questions of fact as to whether Prevagen does not, and cannot, have any impact on memory or brain function.

Based on about 150 years of research, the scientific community has determined that: (a) dietary proteins are digested into common amino acids and, possibly, some small peptides, and (b) with very few exceptions (none of which apply to AQ) neither dietary proteins nor any large peptides that might be produced from their digestion can cross the BBB.

Applying these scientific facts to Prevagen, Plaintiff's expert, Dr. Richard Bazinet, provides opinions that, even if any of the AQ consumed through the ingestion of Prevagen were to survive digestion, enter the bloodstream, arrive at the brain, and then cross the BBB, the amount of AQ that would enter the brain is so trivial that it does not and cannot have any effect on memory or brain function. (D.E. 56-1, Bazinet Report, ¶ 16; Ex. A, Bazinet Dep. 78:4-9, 293:14-25, 309:17-310:4, 319:25-320:22.) As Dr. Bazinet testified, even if one assumes that some AQ could get into the blood and then some could somehow get past the BBB:

> …How on earth do they get to the brain and not the other tissues? And only a small, small, small proportion of those would cross the brain. So we end up with something like zero.

[5] Defendant's assertion that the affirmative evidence Plaintiff provides from Dr. Bazinet is not specific to AQ does nothing to change this. Notwithstanding the substantial evidence discussed in Plaintiff's Motion and the following pages of this response demonstrating that Prevagen and the AQ in it cannot do what Defendant claims, Defendant argues that Dr. Bazinet's opinions are not "based on evidence specific to AQ or Prevagen." (D.E. 55, p. 15.) As explained in greater detail below, however, Dr. Bazinet opines that he does not have to test AQ to reach his conclusion here (an opinion that is unrebutted on the record before the Court on Defendant's motion) and in addition he also relies on the uncontroverted evidence that AQ is a dietary protein no different than any other dietary protein, plus about 150 years of scientific research regarding the digestion of dietary proteins, and the impermeability of the BBB in reaching his opinions. (Ex. A, Bazinet Dep. 65:2-66:10, 120:1-24, 309:17-310:21, 323:21-324:1, 326:3-327:1.) Further, Dr. Bazinet reviewed the documents produced by Defendant, which included testing and studies of AQ conducted or commissioned by Defendant and submissions and statements made to the FDA by Defendant regarding AQ, all of which also support his opinion. (D.E. 56-1, Bazinet Report ¶¶ 31-36.)

> We can do the theoretical calculation, but if we take it forward to its implications, it takes us to zero or meaningfully zero, even by a physicist's definition of zero. If you put four molecules in the blood, for example, the odds of one of those four molecules entering the brain are so close to zero, I can't think of another way to say it.

(Ex. A, Bazinet Dep. 293:15-24).

This opinion is unrebutted. Moreover, Dr. Bazinet's opinions further establish that even this trivial amount of AQ making it into the brain is highly unlikely, for two reasons: First, the 10 mgs of AQ in Prevagen is digested into amino acids and possibly some small peptides that, like amino acids, do not have any more effect on the brain than the amino acids and peptides produced by the other 7490 mgs of protein in the average daily diet. (D.E. 56-1, Bazinet Report, ¶¶ 15-20; Ex. A, Bazinet Dep. 78:4-9, 238:15-239:9, 241:21-243:5, 256:13-259:1, 285:25-286:4, 308:23-310:4, 320:17-22.) Second, even if in the highly unlikely event that some intact AQ or a peptide from it somehow survived digestion, entered the bloodstream, and traveled to the brain, it is highly unlikely that it could pass the BBB. (D.E. 56-1, Bazinet Report, ¶ 23; Ex. A, Bazinet Dep. 78:4-9, 109:4-23, 241:21-243:5, 310:16-310:21.)

Yet, even if one were to set aside Plaintiff's expert report, Defendant's submission to the FDA stating that AQ is digested like all other dietary proteins and is, in Defendant's words, completely digested into "amino acids," constitutes an admission proving that AQ is digested solely into amino acids. (D.E. 58-6, FDA Letter dated 9/2/14 (the "FDA Letter"), pp. 000039, 000040; *see also Spitzer v. Saint Francis Hospital*, 94 F.Supp.2d 423 (S.D.N.Y. 2000) (public documents filed with regulatory agencies are admissions of party opponent); *Pharmacy, Inc. v. Am. Pharm. Partners, Inc.*, No. CIV.A.05-776DRHAKT, 2007 WL 2728898, at *1 (E.D.N.Y. Sept. 14, 2007) (same).

In fact, Defendant's chief scientist, Dr. Daniel Moran made the very same statements in a peer-reviewed article in which he summarized the results of the pepsin digestion study that he and Defendant's president, Mark Underwood, co-authored and published in a peer reviewed journal. (D.E. 58-5, D.E. 58-5, Moran DL, Marone PA, Bauter MR, Soni MG. Safety assessment of Apoaequorin, a protein preparation: subchronic toxicity study in rats. Food Chem Toxicol 2013; 57:1-10 ("2013 Safety Assessment Study"), p. 2, Section 2.2.1.) Based upon these admissions

alone, Plaintiff has more than met his burden, meaning Defendant's motion for summary judgment must be denied.

1. Any AQ that might cross the BBB would be so trivial that it could not have an effect on memory or brain function.

Defendant's motion for summary judgment should also be denied because Plaintiff's evidence has, at a minimum, created material questions of fact that the amount of AQ or any larger peptide (such as Defendant's postulated unique peptide) that might make it to the brain is so trivial that it does not and cannot have any effect on memory or brain function. (D.E. 56-1, Bazinet Report, ¶ 16; Ex. A, Bazinet Dep. 78:4-9, 293:14-25, 310:1-4.) Dr. Bazinet, a highly qualified expert on the issues in this case, makes clear that whether AQ is digested solely into amino acids or mostly amino acids and possibly some small peptides (both of which mean that AQ is completely digested – as there are no remaining AQ molecules) makes no difference with regard to the question at hand. (D.E. 56-1, Bazinet Report, ¶ 15; Ex. A, Bazinet Dep. 64:10-22, 109:10-19, 319:4-319:10.) Under either scenario, digestion of AQ produces the same by-products as any other dietary protein, and, consequently, cannot and does not have any more impact on improving memory or brain function than a hot dog. (D.E. 56-1, Bazinet Report, ¶ 15; Ex. A, Bazinet Dep. 239:8-9.)

At pages 14-16 of its Memorandum, Defendant engages in a compendium of misstatements or overstatements from the record. (D.E. 55, pp. 14-16.) For example, Defendant contends that Dr. Bazinet acknowledged that proteins and peptides can have an effect on the brain without passing the BBB. (D.E. 55, pp. 9, 16.) From this they appear to argue that Dr. Bazinet has not foreclosed that AQ or a peptide from AQ could affect the brain without crossing the BBB. (*Id.*) What Defendant fails to point out is that the question its counsel asked was open-ended and that, as a result, Dr. Bazinet truthfully answered it in the manner that he did, not because he was admitting that proteins outside of the brain affect memory or brain function, but rather because the brain manufactures its own proteins and peptides and these affect the brain without crossing the BBB. (Ex. A, Bazinet Dep. 78:10-79:3 (discussing proteins ***in the brain*** that affect its function without having crossed the BBB), 85:20-86:10 (explaining that things in the brain that did not cross the BBB did not need to because they could be made in the brain), 106:21-108:1 (explaining that things

that are made in the brain, like serotonin transporters, can also be found and ingested through food, but that ingestion will not result in the material crossing the BBB).

Likewise, contrary to Defendant's contention otherwise (D.E. 55, p. 15), Dr. Bazinet does consider the peptides produced by the digestion of AQ. In his report and during his deposition, Dr. Bazinet pointed out that any possible peptides produced by the digestion of AQ would be small – comprised of two to three amino acids – and would have similar traits to amino acids. (D.E. 56-1, ¶ 11, 13, 15; Ex. A, Bazinet Dep. 238:15-239:9, 256:13-257:1, 258:13-259:1, 309:17-310-4.) Defendant also points out that Dr. Bazinet has never tested AQ. (D.E., p. 15.) But, as Dr. Bazinet explained, he did not need to do so since he was relying upon the vast weight of well-settled and universally accepted scientific evidence that dietary proteins like AQ are completely digested (*e.g.*, that after digestion AQ molecules no longer exist and in its place are mostly if not all amino acids and possibly some small peptides). (D.E. 56-1, Bazinet Report, ¶¶ 11, 13; Ex. A, Bazinet Dep. 310:6-21, 322:1-322:13, 324:25-327:1.)

Defendant also attacks Dr. Bazinet's opinions regarding the dilution of the products of AQ's digestion by the other 7490 mg of protein in the average daily intake. (D.E. 55, pp. 15-16.) The 10 mg recommended daily dose of Prevagen represents 1/7,500 or about 0.013% (0.025% for the 20 mg dose) of the daily dietary intake of proteins, and an even smaller fraction of the total proteins because, in addition to ingested proteins, there are endogenous proteins made by the body. (D.E. 56-1, Bazinet Report, ¶¶ 17, 18; Ex. A, Bazinet Dep. 78:4-9, 241:21-243:5.) Thus, any amino acids or small peptides absorbed as a result of ingesting Prevagen would be trivial in comparison to those absorbed in the daily diet, and even more trivial compared to the combination of endogenously produced and ingested proteins in the body. (D.E. 56-1, Bazinet Report, ¶¶ 17, 18; Ex. A, Bazinet Dep. at 78:4-9, 241:21-243:5, 257:2-258:12, 285:25-286:4, 308:23-310:4, 320:17-22.) For example, Dr. Bazinet explained that a hot dog contains about 5000 mg of protein or about 500 times the amount in Prevagen (250 times for the 20 mg dose). (D.E. 56-1, Bazinet Report, ¶ 18; *see also* Ex. A, Bazinet Dep. 285:4-14.) Even a slice of white bread contains over 200 times the amount of protein in a dose of Prevagen (over 100 times for the 20 mg dose). (D.E. 56-1, Bazinet Report, ¶ 18; *see also* Ex. A, Bazinet Dep. 285:4-14.)

Dr. Bazinet also explained that the trivial amount of amino acids or small peptides that might, by sheer randomness, get into the brain as a result of the ingestion of Prevagen would have no clinically significant effect on brain health, memory, or function. (D.E. 56-1, Bazinet Report, ¶ 20; Ex. A, Bazinet Dep. 242:7-243:1, 309:19-310:4.) Further, contrary to Defendant's argument (D.E. 55, p. 8), this is true regardless of when Prevagen is taken. (Ex. A, Bazinet Dep. 307:19-308:22.) Based on its extreme triviality in comparison to the much larger amounts of proteins consumed on a daily basis, Dr. Bazinet opined that claiming that Prevagen provides any brain health benefits is false. (D.E. 56-1, Bazinet Report, ¶ 19; Ex. A, Bazinet Dep. 284:20-285:14.)

Yet, Defendant insists that Dr. Bazinet somehow has not considered that the digestion of AQ could somehow produce a unique peptide that is somehow bioactive and that somehow could affect the brain – with or without entering the brain. (D.E. 55, pp. 7-8, 9, 15-16). As a threshold matter, despite about 150 years of research not one bioactive peptide has been found to be produced by a dietary protein and quite conspicuously, Defendant fails to cite any example of one. (Ex. A, Bazinet Dep. 109:14-19.) Further, Dr. Bazinet considered this possibility in his report, where he stated that AQ would be digested mostly, if not entirely, into amino acids and possibly some small peptides (D.E. 56-1, Bazinet Report, ¶ 13) – so his report, at a minimum, sets forth that it is his opinion that it is not possible, based upon well-settled and universally accepted scientific principles, that AQ would be digested into anything but amino acids and possibly some small peptides – not the hypothetical bioactive peptide that would somehow affect the brain that Defendant postulates. Thus, at best Defendant's argument goes to the weight but does not mean that somehow Plaintiff has failed to meet his burden of proof.

As Dr. Bazinet noted during his deposition, one could also argue that it is at least possible that a pink elephant might walk into one's room in the next minute, but that the probabilities of this happening were, of course, effectively zero. (Ex. A, Bazinet Dep. 244:25-245:13.) The same applies to Defendant's argument here and Dr. Bazinet stated this during his deposition. (Ex. A, Bazinet Dep. 305:16-306:6.)

2. At a minimum, Plaintiff has presented sufficient evidence to create material questions of fact that as a result of digestion, Prevagen, and its AQ, cannot have the claimed effect on memory and brain function.

While triviality alone is sufficient evidence of falsity, Plaintiff also presents evidence that no AQ survives digestion such that oral ingestion of it cannot improve memory or brain function. Indeed, the evidence shows that AQ is a dietary protein and like all other dietary proteins, is fully digested before it hits the bloodstream. (D.E. 56-1, Bazinet Report, ¶ 11; Ex. A, Bazinet Dep. 64:10-22.)

In the course of digestion, enzymes including pepsin (in the stomach), trypsin, elastase, chymotrypsins, and carboxypedidases break down dietary proteins, including AQ, into amino acids and possibly some small peptides for absorption into the intestine, all of which are indistinguishable from other proteins. (D.E. 56-1, Bazinet Report, ¶ 12; Ex. A, Bazinet Dep. 64:10-22, 257:2-259:1.) From this point on, AQ is no longer a calcium-binding protein, and cannot possibly improve memory or brain function, any more than 1/500th of a hot dog could. (D.E. 56-1, Bazinet Report, ¶ 10; Ex. A, Bazinet Dep. 284:20-285:14.)

After initial digestion by pepsin in the stomach what is left then goes through additional digestion in the intestinal cells and is even further reduced. (D.E. 56-1, Bazinet Report, ¶ 14; Ex. A, Bazinet Dep. 247:7-14.) Within the intestine a series of peptidases ensures that any peptides that have entered are converted into amino acids for secretion into the blood where they can be taken up by the liver and metabolized or passed through to the circulatory system. (D.E. 56-1, Bazinet Report, ¶ 14; Ex. A, Bazinet Dep. 141:17-142:4.)

As Dr. Bazinet explained, after about 150 years of study, it is the scientific consensus that dietary proteins get digested and do not enter the blood. (Ex. A, Bazinet Dep. 120:1-24, 322:1-322:13, 326:3-327:1.) The amino acids these common dietary proteins provide are used by the body for any number of purposes, including the synthesis of muscle, tissues, and enzymes. (D.E. 56-1, Bazinet Report, ¶ 15; Ex. A, Bazinet Dep. 77:22-78:3.) Once in the bloodstream, the body does not single out the amino acids from AQ, as opposed to the vast amount of other amino acids from the daily ingestion of dietary proteins, and send them to the brain. (D.E. 56-1, Bazinet Report, ¶ 16; Ex. A, Bazinet Dep. 257:10-14.) Rather, the body uses all amino acids, including those

derived from AQ and all other dietary proteins, as and where needed. (D.E. 56-1, Bazinet Report, ¶ 16.) Accordingly, even if some amino acids from AQ were to enter the brain in any form, it would be purely random and not because AQ naturally directs itself towards the brain. (D.E. 56-1, Bazinet Report, ¶ 16; Ex. A, Bazinet Dep. 258:2-8, 293:14-25.) And even then, as discussed above, it would be trivial in amount. (D.E. 56-1, Bazinet Report, ¶ 16; Ex. A, Bazinet Dep. 78:4-9, 293:14-25, 310:1-4.)

Defendant cannot and does not show how these opinions do not, at a minimum, create material questions of fact on these issues.

3. Defendant's studies and submission to the FDA not only corroborate Dr. Bazinet's opinions but are also admissions that AQ is digested solely into amino acids.

As noted in Plaintiff's Motion (D.E. 58, pp. 6-7), Dr. Bazinet's opinions are corroborated by studies and documents authored by Defendant and its agents – studies and documents Defendant ignores in its Motion. These include digestion studies published in peer-reviewed journals, conducted by Defendant and co-authored by Defendant's President Mark Underwood and Dr. Moran (who is also employed by Defendant), confirm that AQ is readily and easily digested into amino acids like any other dietary protein. (D.E. 56-1, Bazinet Report, ¶¶ 31-33; Ex. A, Bazinet Dep. 139:6-140:6.) They also include a submission Defendant made to the FDA. (D.E. 56-1, Bazinet Report, ¶ 34 (citing to Defendant's GRAS Notification for AQ (filed at D.E. 58-6)).)

In the pepsin digestion study, Mr. Underwood and his co-authors used a standard test/assay relied upon by experts in the field to determine whether a dietary protein is readily digested by pepsin – the first enzyme that dietary proteins meet in the body's stomach. In their own words this study showed that "Apoaequorin is easily digested by pepsin, a characteristic commonly exhibited by many non-allergenic dietary proteins." (D.E. 56-1, Bazinet Report, ¶ 31; Ex. A, Bazinet Dep. 128:8-17, 252:23-25; D.E. 58-4, 2014 Safety Assessment Study, Section 2.5, p. 245.) Also as part of the study, they compared the protein sequence of AQ to other proteins, in part to see if it had any unique properties, and concluded that there was "no added concern of safety due to unusual stability of the protein by ingestion." (D.E. 56-1, Bazinet Report, ¶¶ 31-32; D.E. 58-4, 2014 Safety Assessment Study.) In other words, Defendant's published study report shows that AQ does not

retain any of its AQ-like aspects upon digestion – it is digested like other common proteins (D.E. 56-1, Bazinet Report, ¶ 32), and its amino acid sequence[6] does not show anything out of the ordinary that is not like other dietary proteins.[7] In fact, in another published report authored by Dr. Moran he characterizes the results of the above pepsin study as proving that AQ "is digested or enzymatically hydrolyzed ***to individual amino acids*** that are likely to be absorbed in the digestive tract." (D.E. 56-1, Bazinet Report, ¶ 33; D.E. 58-5, 2013 Safety Assessment Study (emphasis added).)

Similarly, and most importantly, documents submitted to the FDA by Defendant as part of its submission it made in response to a GRAS notification from the FDA not only confirm Dr. Bazinet's opinions but also constitute admissions on Defendant's part that AQ is completely digested into individual amino acids. In this submission, Defendant provided the report of a panel of six digestion experts it had hired, before this litigation, who were asked to and did opine on behalf of Defendant as to how AQ is digested. This report states that the pepsin study (1) "revealed that [AQ] was rapidly digested in pepsin – more than 90% of the protein was digested in less than 30 seconds," with the protein having "nearly disappeared by 120 seconds." Defendant also told the FDA this "suggest[s] that the digestion characteristics of the Apoaequorin are similar to those of common non-allergenic dietary proteins." (D.E. 58-6, pp. 00035, 00037 and 00063.) Similarly, Defendant told the FDA: "In less than 30 seconds, over 90% of Apoaequorin was digested and by 2 minutes almost all of the protein is digested." (D.E. 56-1, Bazinet Report, ¶ 34; D.E. 58-6, FDA Letter.) Finally, Defendant's submission to the FDA incorporated the conclusions of this panel of six experts and states to the FDA that the scientific evidence, including the pepsin study, "suggests that following oral consumption by ***humans***, Apoaequorin is likely to be ***completely*** hydrolyzed to

[6] The amino acid sequence of a protein is merely the order in which a particular dietary protein's amino acids line up. When a protein is digested it is "cleaved" by the digestive enzymes down to its individual amino acids or peptides of two to three amino acids. The amino acids comprising these small peptides would, quite naturally, be in the sequential order that they are found when part of the dietary protein.

[7] With regard to Defendant's "unique" peptide speculation, this means that Defendant's president has said that there is nothing unique about AQ's amino acid sequence which, in turn, debunks Defendant's newly invented unique peptide speculation. When cleaved by digestion any possible peptides that might be cleaved will be in sequences that are produced by all other dietary proteins. (Ex. A, Bazinet Dep. 130:15-131:1, 145:12-20, 257:19-259:1, 289:16-292:1.)

individual amino acids that will be absorbed in a process ***similar to other dietary proteins***." (D.E. 56-1, Bazinet Report, ¶ 34; D.E. 58-6, FDA Letter (emphasis added).)

C. The "facts" Defendant claims support its motion do not show what Defendant claims.

In the Factual Background section of its motion, Defendant presents six supposed "facts" that Defendant contends Dr. Bazinet's deposition testimony "plainly contradicts the key opinions from his expert report." A review of the six supposed "facts" shows that is just not so.

1. Dr. Bazinet is an expert on the issues relevant to this case – including digestion of dietary proteins, whether proteins can cross the BBB, and brain chemistry.

Contrary to Defendant's contentions otherwise, Dr. Bazinet is highly qualified to render the opinions he gives in this matter. The only purported active ingredient in Prevagen is AQ – a dietary protein. (D.E. 40, Defendant's Answer, ¶ 1; D.E. 21-2, Product Label.) Dr. Bazinet has extensively studied dietary proteins. (D.E. 56-1, Bazinet Report, ¶¶ 1-2; Ex. A, Bazinet Dep. 38:15-42:10.) Dr. Bazinet is a nutritional neuroscientist with expertise in lipid and protein digestion. (D.E. 56-1, Bazinet Report, ¶ 1; Ex. A, Bazinet Dep. at 13:1-18, 35:21-37:1, 38:15-39:4.) Dr. Bazinet was personally involved in research attempting to open the blood-brain barrier to allow certain medicinal proteins and peptides to cross into the brain when he was with the National Institutes of Health as a post-doctoral fellow from 2002-2006. (Ex. A, Bazinet Dep. 53:11-54:8, 65:19-66:6.) He has published numerous articles on nutrients and how they enter and are metabolized in the brain. (Doc. 56-1, Bazinet Report ¶ 2.) Dr. Bazinet is currently performing ongoing studies related to nutrition, oral intake of nutrients, and protein digestion. (Ex. A, Bazinet Dep. at 28:7-11, 38:15-24, 39:11-23, 41:4-14.) He also routinely collaborates with gastroenterologists in his department on nutrition and digestion issues. (*Id*. at 18:6-12, 22:12-16, 47:17-50:4, 322:17-323:16.) And in forming his opinions in this case, Dr. Bazinet reviewed studies of AQ and submissions Defendant made to the FDA regarding AQ that support his opinion. (D.E. 56-1, Bazinet Report ¶¶ 31-36.)

Despite this, Defendant claims that Dr. Bazinet is not an expert on Prevagen or AQ, since he has not studied or worked with either of them. (D.E. 55, p. 5.) This is, of course, irrelevant, as Dr. Bazinet's credentials demonstrate he is an eminently qualified expert on dietary proteins, their

digestion, and whether they can cross the BBB.[8] And since, as Dr. Bazinet explained in the full answer to a question cited by Defendant, the AQ in Prevagen is indistinguishable from other dietary proteins (Ex. A, Bazinet Dep. 256:13-257:18), Dr. Bazinet's opinions here are relevant, and establish that, as explained above, Prevagen and the AQ in it are completely digested. Further, as discussed below, Dr. Bazinet has opined that he does not need to test AQ to reach the conclusions he reaches as there is a vast scientific literature supporting them.

2. AQ, like other dietary proteins, is completely digested.

Defendant disputes that AQ is fully digested, claiming Dr. Bazinet "repeatedly admitted in deposition that AQ is not 'completely' or 'fully' digested as stated in his report but that AQ is broken down into *both* single amino acids *and* small chains of amino acids, called peptides." (D.E. 55, pp. 5-6.) However, this is, by definition, complete digestion – AQ no longer exists and in its place are amino acids and peptides.

But Defendant argues that this means that Plaintiff has failed to prove an essential element of his claim because Dr. Bazinet agreed that peptides could either affect the brain without crossing the BBB or could cross the BBB and affect brain function. (D.E. 55, pp. 15-16.) This mischaracterizes Dr. Bazinet's testimony, attributes unheard of characteristics to AQ without supporting evidence, and ignores what Plaintiff is actually required to prove.

First, that Dr. Bazinet stated that proteins or peptides might affect the brain without crossing the blood brain barrier does not mean that dietary proteins, like AQ, can affect the brain from outside the brain. Rather it merely reflects a truism – that the brain makes its own proteins and peptides that affect its health and function and that these do not cross the BBB. (D.E. 56-1, Bazinet Report, ¶ 22.) Furthermore, that he testified, consistent with his report, that certain rare peptides that were either man-made or endogenously produced by the body can cross the BBB (D.E. 56-1, Bazinet Report, ¶ 24; Ex. A, Bazinet Dep. 142:2-142:16), does not mean that peptides produced by dietary proteins like AQ can pass the BBB. (D.E. 56-1, Bazinet Report, ¶ 25; Ex. A, Bazinet Dep. 59:15-17, 310:6-21, 323:21-324:1, 30:23-321:25.)

[8] Indeed, Dr. Bazinet's most recent publication, published after his deposition, further confirms this. http://www.ncbi.nlm.nih.gov/pubmed/26633472

Second, accurately stated, Dr. Bazinet concludes in his report and stated at his deposition that AQ, like other dietary proteins, is completely digested *because* it no longer exists after digestion, having been reduced to all or mostly amino acids and possibly some small peptides. (D.E. 56-1, Bazinet Report, ¶ 30.) Because the AQ has been broken up such that there are no intact AQ molecules left, this is, on its face, complete or full digestion. As Dr. Bazinet stated in his report and repeatedly stated again during his deposition this is what happens to every dietary protein, including AQ – they are completely digested into amino acids and possibly a few small peptides before reaching the bloodstream. (*See, e.g.*, D.E. 56-1, Bazinet Report, ¶¶ 11, 13; Ex. A, Bazinet Dep. 64:15-22, 119:2-120:24, 256:13-257:18, 322:1-13.)

Defendant says it is critical that digestion of AQ may result in peptides, since "Dr. Bazinet admits that peptides can affect brain function." (D.E. 55, p. 5.) But, again, Defendant confuses the general proposition that peptides can affect brain function with whether or not any peptides produced by the digestion of AQ could affect the brain. On the latter, Dr. Bazinet is clear – there are none. But of course there are peptides that affect the brain – the brain makes peptides. So Dr. Bazinet's answer to this question is ***both*** true ***and*** entirely consistent with his opinions in this case.

Further, as Dr. Bazinet explains in his report and his deposition, the peptides produced as a result of digestion of AQ, like other dietary proteins, would be small – consisting of just two or three amino acids (di or tri peptides). (D.E. 56-1, Bazinet Report, ¶ 11; Ex. A, Bazinet Dep. 238:19-239:9.) Di and tri peptides are ubiquitously produced by the digestion of all dietary proteins and are indistinguishable from one another. (D.E. 56-1, Bazinet Report, ¶¶ 11, 16; Ex. A, Bazinet Dep. 238:19-239:9, 256:13-258:12.) And it is the commonness of the peptides produced as a result of digestion of AQ and other dietary proteins that means that the 10 or 20 milligrams of AQ in Prevagen would provide "the same amount of amino acids, dietary amino acids and dietary peptides and dietary protein as a small piece of hotdog or a piece of bread." (Ex. A, Bazinet Dep. 285:8-14; *see also* 256:13-258:12, 309:17-310:4, 319:25-320:22.)

Defendant then criticizes Dr. Bazinet's opinions because he did not test AQ, and therefore, Defendant claims, "he has no knowledge of the peptides resulting from digestion of AQ or how AQ may compare to other dietary proteins in this respect." (D.E. 55, p. 6.) Dr. Bazinet testified

that there is no need to do laboratory testing of AQ because he is relying upon a vast weight of scientific evidence and literature that demonstrates that AQ would be fully digested just like any other dietary protein. (*See, e.g.*, D.E. 56-1, Bazinet Report, ¶¶ 11, 30; Ex. A, Bazinet Dep. 120:1-24, 310:6-310:21, 323:17-324:1, 326:3-327:1.) "So the way this works is this has been studied now for about 150 years, and it's the consensus of all the fields that dietary proteins get digested and don't enter the blood." (Ex. A, Bazinet Dep. 109:14-19.)

Unrebutted in the record on this motion is Dr. Bazinet's opinion that Defendant's arguments about the possibility that Prevagen capsules could somehow delay digestion of AQ is irrelevant. (D.E. 55, p. 7.). As Dr. Bazinet explained, any theoretical delay is irrelevant since at best it merely would delay digestion not prevent it. (Ex. A, Bazinet Dep. 126:22-127:9, 307:19-308:22.)

Finally, Defendant claims that Dr. Bazinet testified "he is aware of reports showing the existence of proteins that are resistant to pepsin…and has not ruled out the possibility that AQ could be a pepsin resistant protein." (D.E. 55, p. 7 (citing Bazinet Dep. 133:23-134:10).) First, as noted above, Defendant has admitted in multiple documents, including ones submitted to the FDA, that AQ is not pepsin resistant.

But on this point, Defendant asked Dr. Bazinet if he had "any opinion as to whether AQ is a pepsin resistant protein." Dr. Bazinet responded "No" because it is a non-issue, since his opinion is that AQ is completely digested after it passes through both the stomach and the GI tract. (D.E. 56-1, Bazinet Report, ¶¶ 12-15, 31-32.) Even then, later in the deposition, Dr. Bazinet was clear that there is no evidence that AQ is a pepsin resistant protein. (Ex. A, Bazinet Dep. 318:11-155.) Thus, whether or not AQ is completely digested by pepsin in the stomach is a red herring. Nonetheless, both in its submission related to the FDA and in the published report on its pepsin study, Defendant, Dr. Moran, and Defendant's president, Mark Underwood, stated that "[AQ] is easily digested by pepsin…" (D.E. 56-1, Bazinet Report, ¶ 32 (citing Moran DL, Tetteh AO, Goodman RE, Underwood MY. Safety assessment of the calcium-binding protein, apoaequorin, expressed by Escherichia coli. Regul Toxicol Pharmacol 2014;69:243-9); D.E. 58-4, 2014 Safety Assessment Study; D.E. 58-5, 2013 Safety Assessment Study; D.E. 58-6, GRAS notice submission.)

3. The amount of amino acids and peptides generated by ingesting Prevagen is trivial and has no effect on memory or brain function.

Dr. Bazinet's opinion is that whatever is left after AQ is digested (be it amino acids or a combination of mostly – at least over 90%, if not 100% – amino acids and possibly some small peptides), it is too trivial to affect memory or support brain function. (D.E. 56-1, Bazinet Report, ¶ 16-20; Ex. A, Bazinet Dep. 78:4-9, 241:21-243:5, 309:19-310:4, 319:25-320:22.) This opinion stands unrebutted.

Moreover, as Dr. Bazinet stated at his deposition, giving Defendant the benefit of all doubts and assuming that AQ acts like certain rare proteins and some amount of AQ passes into the bloodstream and somehow crosses the BBB, whatever would make it into the brain would be so trivial that it would be meaningless:

> You end up with a dose of molecules -- and I've estimated this….So you have something called a mole, and then you have a minimole, and then you have a micromole, and then you have a nanomole, and then you have a phentomole, and then you have an atomole, and then you have a zeptomole. And a zeptomole is kind of the end. Somewhere in the zeptomole range we hit zero molecules. … You would apply the dose of AQ, 10 milligrams, multiply it by the absorption; then you multiply it by the theoretical maximal absorption. And you end up with some level of zeptomole levels of molecules in the brain. So is that theoretically possible? Well, we can't measure it. It would be completely meaningless … It would be scientifically nothing…. Trillions and Trillions of times beyond what we call nothing in biology.

(Ex. A, Bazinet Dep. 242:4-243:5.)

In response to this, Defendant asserts that it might be "mathematically possible for a unique small peptide (small enough to cross the BBB) to be generated by a partial digestion of AQ." (D.E. 55, pp. 7, 15 (citing Bazinet Dep. 299:11-22, 261:18-263:8).) Once again, Defendant misquotes and takes Dr. Bazinet's testimony out of context. In fact, the cited testimony says nothing about peptides small enough to cross the BBB, much less anything about AQ generating such a peptide. (Ex. A, Bazinet Dep. 299:11-22, 261:18-263:8.) The first passage cited, starting at page 261, starts with a discussion of the types of molecules, not peptides, that might be able to cross the BBB and then ends with a discussion of the size of amino acids and the ubiquitous small di and tri peptides being of a small enough size to pass through the BBB, but as Dr. Bazinet points out most amino acids that make up these peptides are not lipid soluble – meaning that they cannot pass through the

BBB. (D.E. 56-1, Bazinet Report, ¶ 22; Ex. A, Bazinet Dep. 261:2-264:3.) And, of course, there is no discussion of any unique peptide crossing the BBB let alone one produced by the digestion of AQ.

In the second passage, on page 299, while Dr. Bazinet did agree that there is a "mathematical" possibility of AQ generating a unique peptide, this answer is taken completely out of context. In the preceding pages of testimony he made clear that the odds of such a peptide existing are very low because of all the overlap from the dietary proteins and that, at most, one could assume that there might be one obscure tripeptide produced randomly but that, by definition, it would be obscure/trivial in amount. (Ex. A, Bazinet Dep. 298:21-299:10.) Again, despite Defendant's claims, not one mention in either passage of whether this obscure peptide would ever cross the BBB.[9]

The idea that somehow AQ could produce a unique peptide that might be able to pass the blood brain barrier and then actually improve memory or brain function is a spurious contention for other reasons. First, this same speculative "logic" could be applied to any dietary protein. Yet, despite about 150 years of intensive research by the scientific community, Defendant cannot and does not cite to any known unique peptides produced by dietary proteins that cross the BBB or that have any effect on memory or brain function. As such Dr. Bazinet's testimony in this regard is unrebutted.

Similarly, Defendant claims that Dr. Bazinet "testified that dietary proteins may contain 50 different types of amino acids." (D.E. 55, p. 8 (citing Bazinet Dep. 287:15-288:2).) Defendant is confused. Dr. Bazinet testified that there are 20 amino acids. (Ex. A, Bazinet Dep. 290:2-12.) The testimony Defendant cites to is about something completely different - amino acid ***residues***, not amino acids. (Ex. A, Bazinet Dep. 287:15-288:2.) This is a critical distinction that dooms

[9] Defendant also notes that Dr. Bazinet only "eyeballed" AQ's amino acid sequence and could not remember any particular portion of it. (D.E. 55, p. 7.) This is because Dr. Bazinet knew that digestion of AQ destroyed the sequence from the start. Indeed, the questions regarding AQ's amino acid sequence only arose in the context of a hypothetical in which AQ "bypassed" digestion and was instead injected and then whether the injected AQ might bind to a particular receptor. (Ex. A, Bazinet Dep. 243:8-19.) In response to this hypothetical – for which there is no evidence whatsoever could ever happen as a result of a consumer ingesting a dose of Prevagen – Dr. Bazinet explained why the AQ still would not bind to the receptor and cross the BBB. (*Id.*)

Defendant's speculations about the numerous possible combinations of amino acids from 50 amino acids when there are only 20. Moreover, after making this mistake, Defendant launches into a full page of its own speculation about how so many combination from 50 amino acids might produce a unique peptide, when as noted above Dr. Bazinet clearly testified that it was highly unlikely and if there were some randomly produced it would be obscure – *e.g.*, trivial.

Finally, Defendant asserts that Dr. Bazinet failed to consider the recommended timing for taking Prevagen, early in the morning before eating, which Defendant argues would separate the consumption of the 10 or 20 mg of dietary protein it sells from the consumption of the other 75,000 mg of proteins consumed in the average diet. But the fact is when asked about this at his deposition, Dr. Bazinet clearly stated that this would have no impact – because the AQ in Prevagen is digested just like any other dietary protein and it makes no difference when it is eaten/taken. (Ex. A, Bazinet Dep. 307:19-308:12.)

4. Whatever peptides might result from digestion of Prevagen and the AQ in it cannot pass the BBB and affect neuron function.

Defendant notes that Dr. Bazinet "readily conceded" during his deposition that peptides can cross the BBB and affect neuron function. (D.E. 55, p. 8.) While true, this only tells half the story. Dr. Bazinet did state that "certain" peptides could pass the BBB. (Ex. A, Bazinet Dep. 59:3-14, 142:2-16.) The other half of the story, however, is that Dr. Bazinet also clearly stated that these peptides are either endogenously made in the body or man-made synthesized peptides - Dr. Bazinet certainly did not state that there are peptides known to cross the BBB that are generated by the digestion of a dietary protein, let alone by digestion of the AQ in Prevagen. (Ex. A, Bazinet Dep. 58:16-59:17, 142:2-16, 292:17-293:25, 307:19-308:22, 309:17-310:21; D.E. 56-1, Bazinet Report, ¶ 24.) As Dr. Bazinet explains in his report:

> While the scientific literature supporting the fact that proteins do not pass the blood-brain barrier is extensive and is accepted brain chemistry doctrine, there are reports of certain peptides crossing the blood-brain barrier.17 These peptides, however, are the rare exceptions.14-16,18,19,36 They include certain peptides made within the body that are transported into the brain and certain designer peptides that have been engineered by scientists with unique properties that allow them to enter the brain.14-16,18-20

(D.E. 56-1, Bazinet Report, ¶ 24 (endnotes omitted).)

Moreover, Dr. Bazinet never said anything about what effect on brain or neuron function peptides that do cross the BBB might have. While Defendant notes that Dr. Bazinet testified that peptides must "also have high lipid solubility to cross the BBB" (D.E. 55, pp. 8-9 (citing Bazinet Dep. 261:18-263:8)), Dr. Bazinet actually testified that peptides are not very lipid soluble. (Ex. A, Bazinet Dep. 263:3-264:3.) Further, while Dr. Bazinet did testify that "some small polypeptides look like they can cross" the BBB, he then went on to explain just how trivial the "small, small fraction" that cross is, explaining that if there were "a million peptides on the one side, one may cross." (Ex. A, Bazinet Dep. 268:5-269:1.) Moreover, these polypeptides are made up of two to three amino acids and have similar properties and effects as the common dietary amino acids. (D.E. 56-1, Bazinet Report, ¶ 11, 28; Ex. A, Bazinet Dep. 238:15-239:9, 239:18-24.)

Defendant's claim that Dr. Bazinet testified there may be receptors that allow peptides derived from AQ to cross the BBB completely misrepresents what he actually said and this is apparent from the testimony cited by Defendant. (Ex. A, Bazinet Dep. 238:19-239-9 (noting "we've got to be very careful of the definition of peptides because they vary by chemistry and nutrition digestion" and then explaining: "The amino acids and the polypeptides of AQ behave just like the dietary proteins. There's no distinction.").)

Similarly, Defendant's claim that Dr. Bazinet did not rule out the possibility that AQ could bind to a serum protein that could bind to a BBB receptor to transport AQ across the BBB also misrepresents his testimony. Counsel for Defendant posed a hypothetical asking if AQ was *injected*, could Dr. Bazinet rule out the possibility that AQ could bind to a serum protein and then cross the BBB. In answer to this question, Dr. Bazinet stated that he could rule this out because AQ is not injected – it is digested. (Ex. A, Bazinet Dep. 245:15-246:1.)

Finally, Defendant's claim that Dr. Bazinet testified that a single protein or peptide molecule can affect brain function (D.E. 55, p. 9) ignores the direct answer to the question, where Dr. Bazinet testified: "Not a measurable effect, I don't think." (Ex. A, Bazinet Dep. 277:10-15.) This is, of course, entirely consistent with the opinions that he has offered in this case, which stand unrebutted.

5. To affect brain function, AQ or any peptides resulting from it must cross the BBB.

Defendant next claims "Dr. Bazinet testified that proteins and peptides can affect memory directly without crossing the BBB." (D.E. 55, p. 9 (citing Bazinet Dep. 79:2-7, 75:4-76:7).) Again, as discussed above, Dr. Bazinet's answer to the question posed does not mean that dietary proteins and peptides can affect memory directly. Rather it just represents the truism that the proteins and peptides that are made in the brain affect it but do not cross the BBB.

Moreover, though Defendant cites the testimony that bookends a full discussion of this question, Defendant ignores Dr. Bazinet's full testimony, where he clearly states that there are no molecules or peptides that directly support brain health or function while being outside of the brain, but that there are numerous ones inside the brain that never cross the BBB (because they are made in the brain) that do affect memory. (Ex. A, Bazinet Dep. 76:23-79:5.) As Dr. Bazinet also explained, there are substances that can "effect" the brain or memory, without crossing the BBB, but this is because of the broad meaning of effect. Dr. Bazinet noted that a drug that stopped or slowed the heart would decrease blood flow to the brain, thereby having an effect on it without crossing the BBB. (Ex. A, Bazinet Dep. 72:10-75:3.) Similarly, when he was asked later in his deposition if AQ has to enter the brain to improve brain function, Dr. Bazinet was just as clear about AQ specifically, explaining:

> So the way Quincy on its website and other places suggests AQ would work, not only would it have to enter the brain, but it would have to enter very specific parts of the brain for that theoretical discussion to happen.
>
> If you're going to be a calcium-binding protein in neurons that are disregulating with age, yes, the theory that's presented here on how this would work, there's no way I can dream up that's remotely realistic that it could work outside of the brain.

(Ex. A, Bazinet Dep. 283:18-284:2.) Furthermore, as Dr. Bazinet made clear in his report, AQ loses its calcium binding protein attributes upon digestion. (D.E. 56-1, Bazinet Report, ¶ 10.)[10]

[10] Defendant then goes on to discuss how peptides can have functional, rather than nutritional, properties, and affect brain function without crossing the BBB. Here again, as Dr. Bazinet explained during his deposition, Defendant is confusing dietary proteins and proteins. (*See, e.g.*, Ex. A, Bazinet Dep. 272:2-273:25 (discussing the "tons of peptides in the body" and insulin, in particular).) Finally, Defendant ambiguously states that Dr. Bazinet stated that it was possible for proteins and peptides to act as "signaling molecules" but never asked what this meant and Dr.

6. Dr. Bazinet properly criticized Defendant's attempts to rely on animal studies to support its claims regarding Prevagen.

Lastly, Defendant contends that Dr. Bazinet's critiques of Defendant's reliance on animal studies to support its claims regarding Prevagen is undermined by his use of animal studies in his own work. (D.E. 55, pp. 9-10.) First, Defendant has not cited to one animal study in support of its motion. So, whatever bearing they may or may not have on this case, the question of whether animal studies can be relied upon to draw conclusions about what happens in humans has nothing to do with Defendant's motion.

Moreover, Dr. Bazinet discussed a few animal studies in his report because one week prior to his report being filed, Defendant produced documents that purported to report the results of several studies done in rats and dogs with AQ. As Dr. Bazinet's report makes clear, he was merely commenting on these in case Defendant cited to or relied upon any of them in its motion. They did not. So whatever the merits of this debate are, they are irrelevant for purposes of this motion. And, to the extent that the debate matters, it does not support Defendant's argument. As Dr. Bazinet explained when asked about animal studies, they are useful for forming hypotheses, not conclusions, about humans. (Ex. A, Bazinet Dep. 156:13-22, 315:24-318:10.) That is the sole record upon which Defendant can cite for purposes of its motion.

Defendant also claims that Dr. Bazinet ignored the results of a study of 24 dogs that showed AQ improved cognitive enhancement. (D.E. 55, p. 10.) Here again, whether he did or not has nothing to do with whether Defendant's motion is meritorious. The study, however, made clear that its sole purpose was to study AQ's effects in aged dogs and, by its own language, was not even intended to be used to extrapolate what might happen in humans. Indeed, the title of the study was "A novel mechanism for cognitive enhancement in aged dogs." (Milgram NW, Landsberg G, Merrick D, Underwood MY. A novel mechanism for cognitive enhancement in aged dogs. Journal of Veterinary Behavior, 2015, 10:3.) Since it was an "efficacy" study in aged dogs, both the record and Dr. Bazinet's testimony about this study show it had nothing to do with any body chemistry

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Bazinet's full answer shows that all dietary proteins produces these sorts of molecules. (Ex. A, Bazinet Dep. 274:5-276:3.)

issues at all. (Ex. A, Bazinet Dep. 223:7-227:23.) Since Defendant markets Prevagen to humans and not aged dogs, and since the Court has limited the issues in this phase of the case to body chemistry issues this is irrelevant.

D. Defendant's expert reports should not be considered in connection with Defendant's motion.

The Court's scheduling order provided for the designation of experts whose opinions would be relied upon in support of motions for summary judgment on September 14, 2015. (D.E. 45, 47.) On that date, Plaintiff disclosed Dr. Bazinet, while Defendant chose not to disclose any experts. Thereafter, Defendant disclosed four experts solely as rebuttal experts to Dr. Bazinet. Because the schedule provided for disclosure of rebuttal experts after the filing of motions for summary judgment, Defendant did not rely on any of the opinions offered by those experts in its motion and should not be allowed to rely on those opinions in its reply. *Provenz v. Miller*, 102 F.3d 1478, 1483 (9th Cir.1996), cert. denied, 522 U.S. 808, 118 S.Ct. 48, 139 L.Ed.2d 14 (1997); *Contratto v. Ethicon, Inc.*, 227 F.R.D. 304, 309 (N.D. Cal. 2005).

E. Plaintiff is not required to prove that Defendant knew or should have known that its representations were false to succeed on its claims.

Finally, Defendant argues that to establish liability under fraud-based claims, Plaintiff must show that Defendant knew or should have known that its brain health representations were false. (D.E. 55, p. 17.) The law is well settled that knowledge/intent is not an element of UCL and CLRA fraud based claims.

The California Supreme Court has explicitly held that claims brought under the fraudulent prong of the UCL, in contrast to common law fraud claims, do *not* require proof that the defendant knew its representations were false. As the court explained in *In re Tobacco II Cases*:

> The fraudulent business practice prong of the UCL has been understood to be distinct from common law fraud. A common law fraudulent deception must be actually false, known to be false by the perpetrator and reasonably relied upon by a victim who incurs damages. None of these elements are required to state a claim for injunctive relief under the UCL.

46 Cal. 4th 298, 312, 207 P.3d 20, 29 (2009) (internal quotation marks, alteration, and citation omitted). *Accord Berger v. Home Depot USA, Inc.*, 741 F.3d 1061, 1068 (9th Cir. 2014) ("Actual falsehood, the perpetrator's knowledge of falsity, and perhaps most importantly, the victim's

reliance on the false statements – each of which are elements of common-law fraud claims – are not required to show a violation of California's UCL." (citing *Tobacco II*, 46 Cal. 4th at 312)); *Rubio v. Capital One Bank*, 613 F.3d 1195, 1204 (9th Cir. 2010) (citing *Tobacco II* and stating that deception under the fraudulent prong of the UCL "need not be intended").

Both *Kowalsky* and *Baba*, which Defendant relies on, quote verbatim the portion of *Tobacco II* stating that proof of defendant's knowledge of falsity is not required under the UCL. *See Kowalsky*, 771 F. Supp. 2d at 1160; *Baba*, 2010 WL 2486353, at *7. Further, both *Kowalsky* and *Baba* were product defect cases, and the *Kowalsky* court explicitly relied on that fact in refusing to apply *Tobacco II*. *See Kowalsky*, 771 F. Supp. 2d at 1160. And, unlike here, *Baba* involved a UCL claim based on fraudulent omissions, and discussed the plaintiff's failure to allege knowledge of falsity in that context where knowledge of an omission is a requirement. *See Baba*, 2010 WL 2486353, at *7. Thus, anything in *Kowalsky* and *Baba* requiring proof of a defendant's knowledge of falsity does not apply to Plaintiff's UCL claim based upon Defendants' affirmative misrepresentations.

The same is true for Plaintiff's CLRA claims. *See In re Hydroxycut Mktg. & Sales Practices Litig.*, 299 F.R.D. 648, 658 (S.D. Cal. 2014) (citing *Wilson v. Hewlett-Packard Co.*, 668 F.3d 1136, 1145 (9th Cir. 2012)) ("knowledge is not a requirement to maintain an action based on an affirmative representation" under the CLRA).[11]

III. CONCLUSION

For the foregoing reasons, it is clear that, at a minimum, Plaintiff has carried his burden on his falsity claims as the expert testimony of Dr. Basinet stands unrebutted, Defendant's twisting of his testimony is to no avail, and even Defendant admits that AQ is digested solely into amino acids.

[11] *See also Hovsepian v. Apple, Inc.*, No. 08-5788 JF (PVT), 2009 WL 2591445, at *3 (N.D. Cal. Aug. 21, 2009) (applying *LiMandri v. Judkins*, 52 Cal. App. 4th 326, 336 (1997); *Cirulli v. Hyundai Motor Co.*, No. SACV 08-0854 AG MLGX, 2009 WL 5788762, at *3 (C.D. Cal. June 12, 2009); *Burdt v. Whirlpool Corp.*, No. C 15-01563 JSW, 2015 WL 4647929, at *3-4 (N.D. Cal. Aug. 5, 2015); *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Products Liab. Litig.*, 754 F. Supp. 2d 1145, 1172 (C.D. Cal. 2010) (same); *Falk v. Gen. Motors Corp.*, 496 F. Supp. 2d 1088, 1094-95 (N.D. Cal. 2007).

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CERTIFICATE OF SERVICE

I hereby certify that on December 23 2015, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the Electronic mail notice list, and I hereby certify that I have mailed the foregoing document via the United States Postal Service to the non-CM/ECF participants indicated on the Manual Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on December 23 2015.

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